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(54) Title: NEEDLE RETRACTION MECHANISMS					
(57) Abstract					
<p>There is disclosed a fluid handling device (2) having a needle retraction assembly adapted to bring about the retraction of a hollow needle (10) after use comprising a hollow body portion (4) provided at one end thereof with an end wall having a mounting portion (8) including a needle passage, and a hollow needle (10) having a mounting means and adapted to be movable between a first position in which a leading end portion of the needle protrudes from a front end portion of said mounting portion (8) and a second position in which the needle is withdrawn within the hollow body portion (4), said mounting means including resilient means (28) that act to bias the needle (10) into the second, withdrawn, position, said needle (10) being provided with an enlarged portion (18) at a location spaced from the leading end portion thereof, there being provided retaining means to maintain the needle in its first position until use is completed, said retaining means comprising in combination an O-ring (20) positioned in a circumferential groove (19) in said enlarged portion (18) and abutting the end of a sleeve (36) which can be forced forwardly to dislodge the O-ring (20) so as to permit the needle (10) to move from its first position into its second position under the influence of said resilient means (28).</p>					

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- 1 -

NEEDLE RETRACTION MECHANISMS

The invention is concerned with improvements in or relating to retraction mechanisms for use in fluid handling devices, said mechanisms being arranged to bring about the retraction of a hollow needle into a housing after use. Such devices are used in many facets of the medical field, for the administration of drugs or a drip feed into a blood vessel, or for drawing off liquid samples, for example, blood from patients.

It will be understood that there is a wide range of fluid handling devices incorporating needles in use in the field of medicine for the administration of drugs and the like for blood sampling, including use in procuring more than one sample from a patient over a period of time.

It is important that the needles of such devices, which are frequently intended for disposal after a single use, are rendered inoperative to prevent accidental injury or re-use with the substantial risk of cross-contamination.

Syringes provided with guards of one kind or another which are automatically deployed to shield the needle after use are known, as are syringes where the needle is automatically retracted after use into the body of the device.

The invention provides a fluid handling device having a needle retraction assembly adapted to bring about the retraction of a hollow needle after use comprising a hollow body portion provided at one end thereof with an end wall having a mounting portion including a needle passage, and a hollow needle having a mounting means and

- 2 -

adapted to be movable between a first position in which a leading end portion of the needle protrudes from a front end portion of said mounting portion and a second position in which the needle is withdrawn within the hollow body portion, said mounting means including resilient means that act to bias the needle into the second, withdrawn, position, said needle being provided with an enlarged portion at a location spaced from the leading end portion thereof, there being provided retaining means to maintain the needle in its first position until use is completed, said retaining means comprising in combination an O-ring positioned in a circumferential groove in said enlarged portion and abutting the end of a sleeve which can be forced forwardly to dislodge the O-ring so as to permit the needle to move from its first position into its second position under the influence of said resilient means.

The sleeve may be restrained from rearward movement when the needle is in its first position by a shoulder which abuts a flange at the forward end of the body portion.

The resilient means may be a compression spring located between a forward reaction surface provided by the mounting portion and a rearward reaction surface provided by the forward end of the enlarged portion.

When the needle is in its first position the O-ring may be compressed between the enlarged portion and the mounting portion, which provides a relieved part at its forward end to receive the O-ring when it is dislodged.

- 3 -

The fluid handling device may be a syringe, there being a piston which may be depressed to travel through the body portion to discharge liquid therefrom through the needle, the piston being in the form of a tube having closed ends, the forward of which is provided with a closure member which is separable from the end by engagement with the sleeve as the piston is fully depressed to provide an aperture in the end through which the needle may pass to enter the interior of the piston as it assumes its second position.

The mounting portion may be off-centre and towards a peripheral edge of the body portion.

The cross-sections of the body portion and piston may be such as to prohibit incorrect assembly having regard to the position of the closure member.

The cross-sections of the body portion and piston may be such that whilst permitting assembly in more than one rotational position relative to one another, proper operation is assured, there being more than one closure member in the end of the piston.

The body portion and piston may be of elliptical section, there being two spaced closure members in the end of the piston.

The hollow body portion may not be intended to receive a piston, and a piston-like tool may be inserted into the body portion to cause retraction of the needle into the tool when desired.

- 4 -

The sleeve may be located in a recess accessible by a portion of reduced size on the forward end of the tool adapted to enter the recess to engage with the sleeve. This prevents premature retraction of the needle.

Also in accordance with the invention there is provided a disposable syringe with an off-centre needle and having a body portion and a piston whose forward end includes a closure member adapted to be displaced at the end of the piston stroke to enable a needle retraction mechanism to withdraw the needle and position it within the interior of the piston for disposal.

The cross-sections of the body portion and piston may be such as to prohibit incorrect assembly having regard to the position of the closure member.

The cross-sections of the body portion and piston may be such that whilst permitting assembly in more than one rotational position relative to one another, proper operation is assured, there being more than one closure member in the end of the piston.

The body portion and piston may be of elliptical section, there being two spaced closure members in the end of the piston.

Also according to the present invention there is provided a syringe system comprising a set of syringe barrels with cooperating plungers, comprising barrels and plungers of different capacities, each barrel being adapted to receive a needle mounting and retracting arrangement and each plunger cooperating with the barrel so as to have a part which cooperates with the needle mounting and retracting arrangement aligned

- 5 -

therewith on assembly of the plunger and barrel and the needle mounting and retraction arrangement of at least one of the set being mounted eccentrically so as to permit shallow angle cannulation.

There will now be described two examples of device according to the invention. It will be understood that the description which is to be read with reference to the drawings is given by way of example only and not by way of limitation.

In the drawings :-

Figure 1 is a side view of a syringe according to the invention, in an unused condition;

Figure 2 is a longitudinal section of the syringe taken on line II-II of Figure 1 and to an enlarged scale;

Figure 3 is an end view of the syringe;

Figure 4 is a section on lines IV -IV of Figure 2;

Figure 5 is an opposite end view, being a needle end view;

Figure 6 is a sectional view similar to Figure 1 illustrating an intermediate stage in the depression of a plunger of the syringe;

- 6 -

Figure 7 is a similar view illustrating the completion of the depression step;

Figures 8, 9 and 10 are fragmentary views to an enlarged scale of portions of Figures 2, 6 and 7 respectively;

Figure 11 is a fragmentary longitudinal sectional view of a fluid handling device for taking blood samples;

Figure 12 is a similar view with a needle retraction tool inserted therein;

and Figure 13 is a view of the device with the needle thereof in a retracted condition.

A disposable syringe 2 is shown in Figure 1 comprising a hollow body portion 4, from the rear of which (upper end as viewed in Figures 1) protrudes a piston 6. At the lower end of the body portion 4 is provided a mounting portion 8 for a needle 10, having a through passage at the inner end of which is an upstanding annular wall 9.

The hollow body portion 4, which is non-opaque, is graduated in millilitres for convenience and is provided with finger-engaging flanges 12 in the conventional manner. The body portion 4 has a slightly outwardly flared end portion 15. The mounting portion 8 is secured to an end wall 14 of the body portion 4 in an off-centre

- 7 -

position at 16 (see Figure 2) to facilitate use of the syringe in enabling the needle 10 to penetrate tissue or a blood vessel at as shallow an angle as desired.

The inner end of the needle 10 connects with a collar 18 having an annular groove 19 in which is received an O-ring 20. The collar 18 is bonded to the needle so as to be integral therewith.

As best seen from Figures 3 to 5 the body portion 4 and piston 6 are of elliptical section which avoids any tendency for unwanted relative rotation of the parts.

The mounting portion 8 provides a passageway for the needle 10 and provides a first reaction surface 26 for a compression spring 28 surrounding the needle. A second reaction surface 30 is provided on a forward end of the collar 18. When assembled the spring 28 is in an almost fully compressed condition between the surfaces 26 and 30 and is maintained in that condition by engagement of the O-ring 20, which is compressed between an annular wall portion 32 of the mounting part 8 and its groove 19, with an end surface 34 of a sleeve 36 surrounding the collar 18 and comprising at its rearward end an extension 38, formed by lugs, which project into the hollow body portion 4 in the pre-use condition shown in Figures 2 and 8.

As may be seen in Figure 8, an annular space 35 is provided to the forward side of O-ring 20.

- 8 -

The sleeve 36 has a shoulder 37 which engages an annular flange 39 at the forward end of the body 4 to prevent rearward movement of the sleeve 36 from its initial position shown in Figures 2 and 8.

The piston 6 is hollow having its rear end closed by means of a cap 40. It will be noticed that the diameter of the piston is greatest at the rear end of the piston at 13, that is, adjacent the end cap 40 and tapers inwardly towards the body portion.

The other end of the piston is arranged to receive a closure member 42 which engages firmly in the piston to form an end wall having two areas 44 defined by lines of weakness 46 so as to be readily removed on contact with the sleeve extension lugs 38 in a manner to be explained below. The provision of two such areas 44 obviates the need to check the position of the off-set needle 10 during assembly.

In operation, the syringe is conveniently charged with liquid in a normal manner, to achieve its ready-for-use condition in which the piston 6 is received within the body portion 4 by a short distance as shown in Figure 2. The closure member 42 of the piston thus also acts as a seal for the liquid contents of the body portion.

On actuation of the piston 6 so as to move forwardly (or downwardly as viewed in the Figure 1), the advance of the end wall of the member 42 expels the liquid through the needle 10. Figure 9 shows the position of the parts immediately before the expulsion of the liquid is completed. It will be observed that the end wall of the member 42 has contacted the lugs 38 of the sleeve member 36 and has forced the member 36 forwardly as shown in Figures 9. However, liquid may still pass from the body portion

- 9 -

6 to the needle 10 due to the spaces between the lugs 38 of the member 36. In Figure 10, the movement of the sleeve member 36, because of its contact with the O-ring 20 that is received in the groove 19, has caused the collar 18 also to move forwardly, further compressing the spring 28 to a fully compressed state. In addition, this movement causes the O-ring 20 to be released from entrapment in the groove 19 by the annular portion 32 and to be dislodged to enter the annular space 35, where it is received over the wall 9 of the mounting portion 8. Thus the restraint acting upon the needle end portion 18 is removed. The fully compressed spring 28 is now no longer constrained and extends rapidly, propelling the needle end portion 18 and therefore also the needle itself rearwardly. The sleeve member 36 and its lugs 38 are together of such a length as still to project into the hollow interior of the body portion 4. The lugs therefore provide a pressure area against the area 44 so as to shear the line of weakness 46. The needle 10 is thus free to pass through the sleeve member 36 into the hollow interior of the piston 6, so that the needle is withdrawn from access by potential re-users of the syringe. It will be understood that the piston 6 cannot in practice readily be withdrawn from the body portion 4 to facilitate access to the needle, since the annular portion 13 of the piston 6 is firmly wedged into the flared end portion 15 of the body portion 4 and thus resists removal.

The syringe may therefore now be disposed of without risk to persons subsequently handling the needle.

Figure 11 shows a fragmentary view of a needle retraction mechanism indicated at 48, for use in a device for taking repeated blood samples. The device comprises an open-ended housing 50 into which is inserted an evacuated tube 52 of the

- 10 -

kind sold under the Registered Trade Mark "Vacutainer", having a diaphragm 54 which is pierced by a rear end portion 56 of a double-ended hollow needle 58 so that the sample may be drawn into the tube 52. Conveniently, the needle 58 may remain in place during the period of time in which it may be necessary to take a series of samples, but when the series is completed, the needle must be removed and the risks associated with used needles then arise.

The needle retraction mechanism of the device of Figures 11 to 13 is similar in many respects to that shown in the syringe of Figures 1 to 10, like parts being indicated by like reference numerals.

The needle 58 which as mentioned above is double-ended and passes through the collar 18.

A recessed portion 82 is formed in forward wall of the housing 50 which has a surface 86 against which the evacuated tube 52 abuts in normal use. Thus in normal use, it will be observed, no contact is made by the tube 52 with the lugs 38.

Figure 12 illustrates the means by which the needle 58 may be retracted out of an operative condition and into a position which it cannot be used again nor can it injure anyone handling it.

Thus when the final sample has been taken and the needle of the device needs to be removed from the patient's arm, a tool 88 is inserted into the housing 50 as shown in Figure 12. The tool 88 comprises plunger-like hollow body portion 90 and an

- 11 -

annular projection or neck 92 that is surrounded by a shoulder surface 94. The neck 92 has a circular opening 96. As the tool 88 is inserted into the housing 50, the needle end portion 56 enters the opening 96 in the neck 92 and the neck itself enters the recess 82 in the housing 50. The leading edge surface of the neck 92 contacts the lugs 38 and continued pressure applied to move the tool forwardly as shown in Figure 12 causes the sleeve member 36 to move forwardly to dislodge the O-ring 20 to release the needle 58 for discharge into the body of the tool 88. A snap-on ring clip 98 around the tool 88 ensures that the tool is not accidentally removed from the housing 50 before safe disposal.

Various modifications may be made within the scope of the invention as defined by the following claims.

- 12 -

CLAIMS

1. A fluid handling device having a needle retraction assembly adapted to bring about the retraction of a hollow needle after use comprising a hollow body portion provided at one end thereof with an end wall having a mounting portion including a needle passage, and a hollow needle having a mounting means and adapted to be movable between a first position in which a leading end portion of the needle protrudes from a front end portion of said mounting portion and a second position in which the needle is withdrawn within the hollow body portion, said mounting means including resilient means that act to bias the needle into the second, withdrawn, position, said needle being provided with an enlarged portion at a location spaced from the leading end portion thereof, there being provided retaining means to maintain the needle in its first position until use is completed, said retaining means comprising in combination an O-ring positioned in a circumferential groove in said enlarged portion and abutting the end of a sleeve which can be forced forwardly to dislodge the O-ring so as to permit the needle to move from its first position into its second position under the influence of said resilient means.
2. A fluid handling device according to claim 1 wherein the sleeve is restrained from rearward movement when the needle is in its first position by a shoulder which abuts a flange at the forward end of the body portion.
3. A fluid handling device according to claim 1 or claim 2 wherein the resilient means is a compression spring located between a forward reaction surface

- 13 -

provided by the mounting portion and a rearward reaction surface provided by the forward end of the enlarged portion.

4. A fluid handling device according to any one of claims 1 to 3 wherein when the needle is in its first position, the O-ring is compressed between the enlarged portion and the mounting portion, which provides a relieved part at its forward end to receive the O-ring when it is dislodged.

5. A fluid handling device according to any preceding claim being a syringe, there being a piston which may be depressed to travel through the body portion to discharge liquid therefrom through the needle, the piston being in the form of a tube having closed ends, the forward of which is provided with a closure member which is separable from the end by engagement with the sleeve as the piston is fully depressed to provide an aperture in the end through which the needle may pass to enter the interior of the piston as it assumes its second position.

6. A syringe according to claim 5 wherein the mounting portion is off-centre and towards a peripheral edge of the body portion.

7. A syringe according to claim 6 wherein the cross-sections of the body portion and piston are such as to prohibit incorrect assembly having regard to the position of the closure member.

8. A syringe according to claim 6 wherein the cross-sections of the body portion and piston are such that whilst permitting assembly in more than one rotational

- 14 -

position relative to one another, proper operation is assured, there being more than one closure member in the end of the piston.

9. A syringe according to claim 8 wherein the body portion and piston is of elliptical section, there being two spaced closure members in the end of the piston.

10. A fluid handling device according to any one of claims 1 to 4 wherein the body portion is not intended to receive a piston, there being a piston-like tool insertable into the body portion to cause retraction of the needle into the tool when desired.

11. A fluid handling device according to claim 10 wherein the sleeve is located in a recess accessible by a portion of reduced size on the forward end of the tool adapted to enter the recess to engage with the sleeve.

12. A disposable syringe with an off-centre needle and having a body portion and a piston whose forward end includes a closure member adapted to be displaced at the end of the piston stroke to enable a needle retraction mechanism to withdraw the needle and position it within the interior of the piston for disposal.

13. A disposable syringe according to claim 12 wherein the cross-sections of the body portion and piston are such as to prohibit incorrect assembly having regard to the position of the closure member.

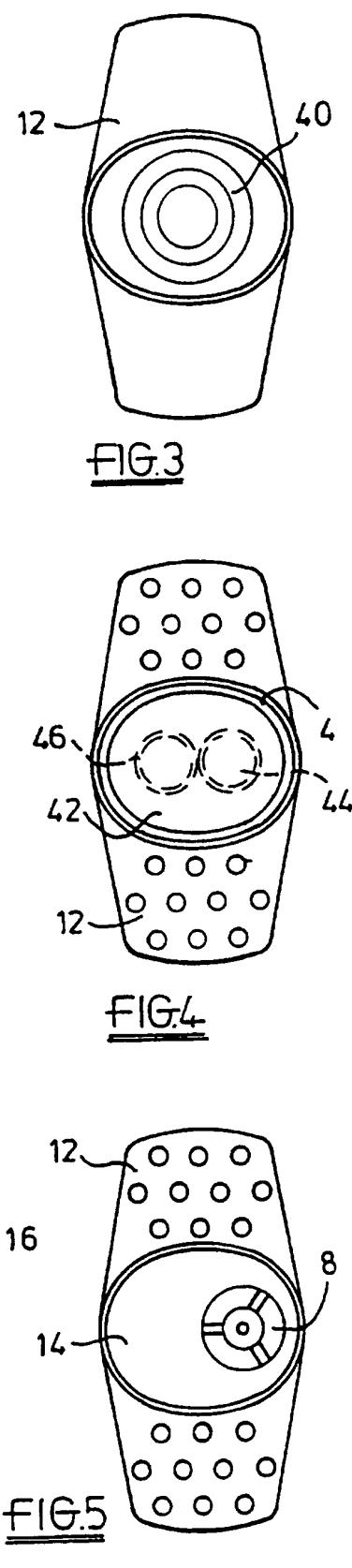
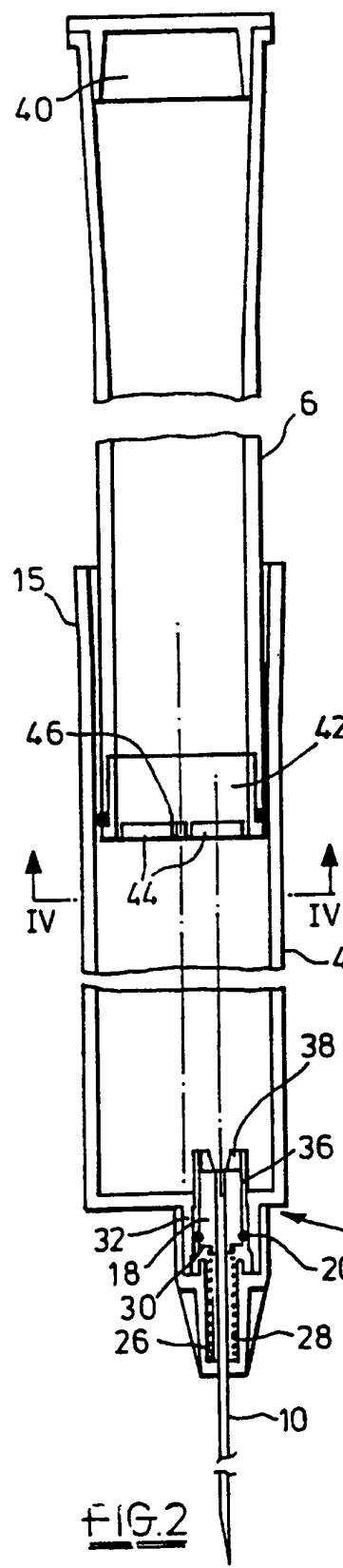
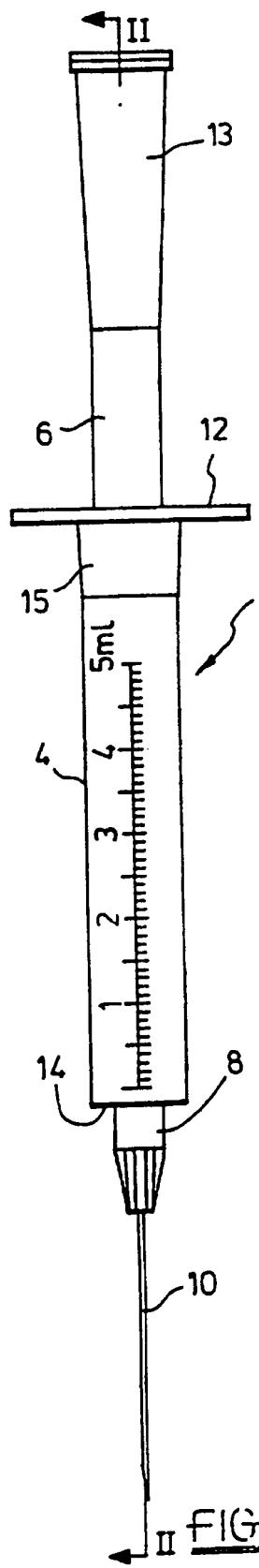
14. A disposable syringe according to claim 12 wherein the cross-sections of the body portion and piston are such that whilst permitting assembly in more than one

- 15 -

rotational position relative to one another, proper operation is assured, there being more than one closure member in the end of the piston.

15. A disposable syringe according to claim 14 wherein the body portion and piston are of elliptical section, there being two spaced closure members in the end of the piston.

16. A syringe system comprising a set of syringe barrels with cooperating plungers, comprising barrels and plungers of different capacities, each barrel being adapted to receive a needle mounting and retracting arrangement and each plunger cooperating with the barrel so as to have a part which cooperates with the needle mounting and retracting arrangement aligned therewith on assembly of the plunger and barrel and the needle mounting and retraction arrangement of at least one of the set being mounted eccentrically so as to permit shallow angle cannulation.



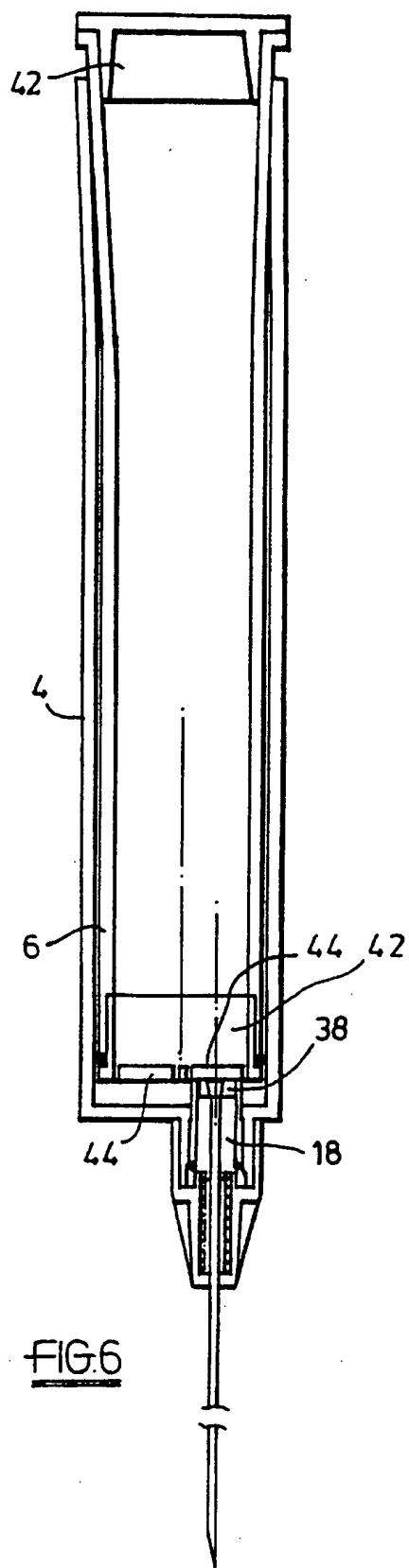


FIG.6

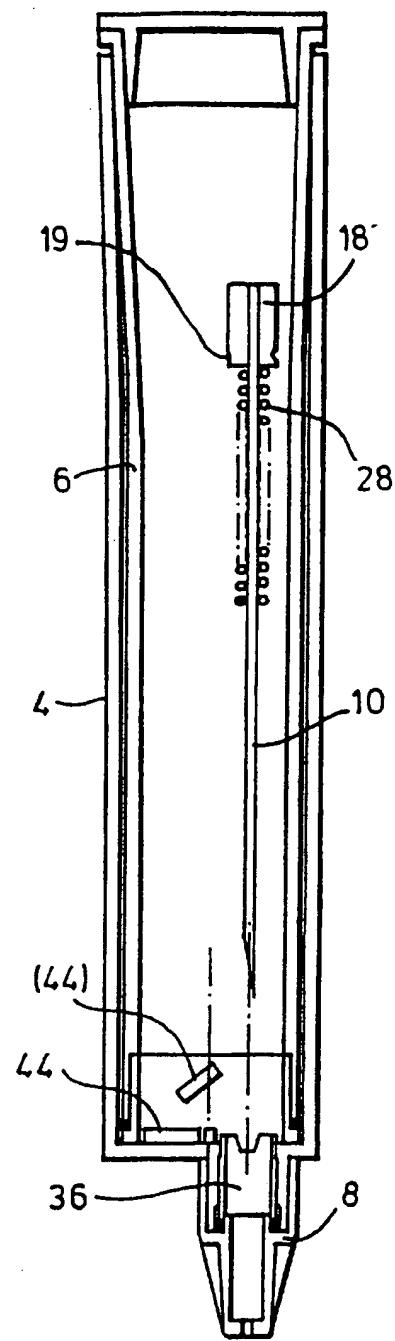


FIG.7

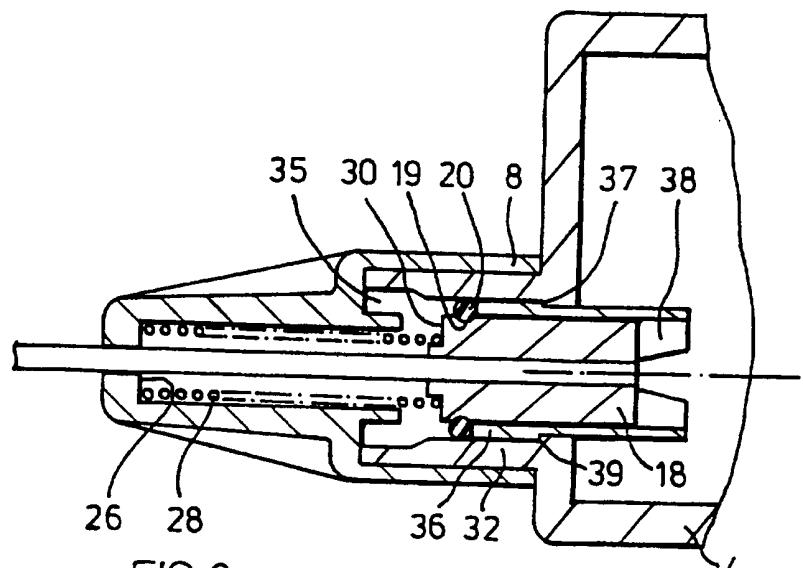


FIG. 8

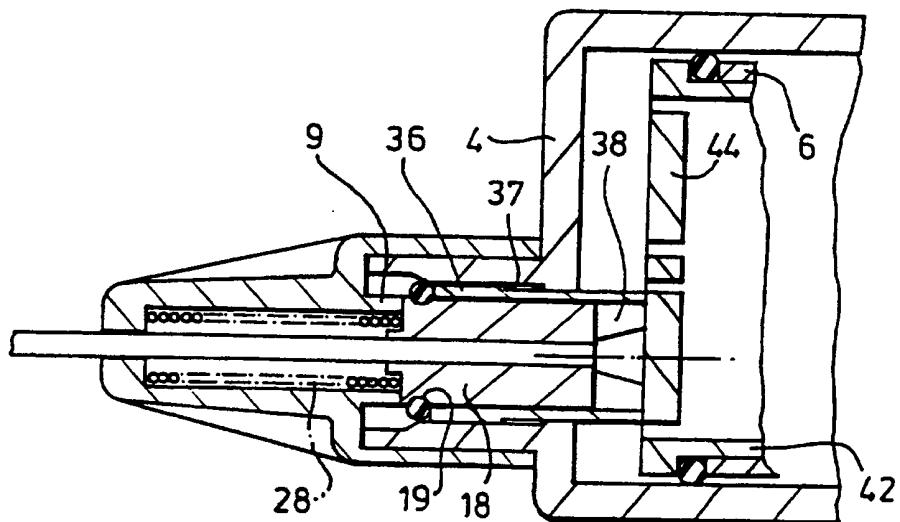


FIG. 9

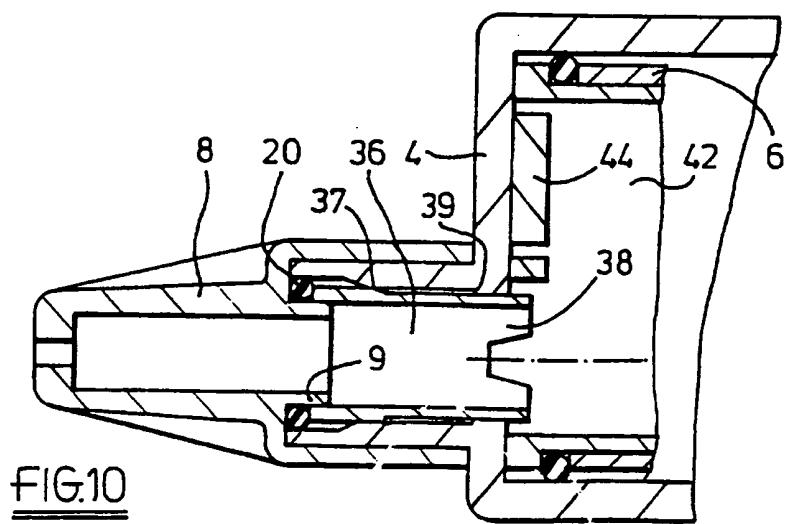
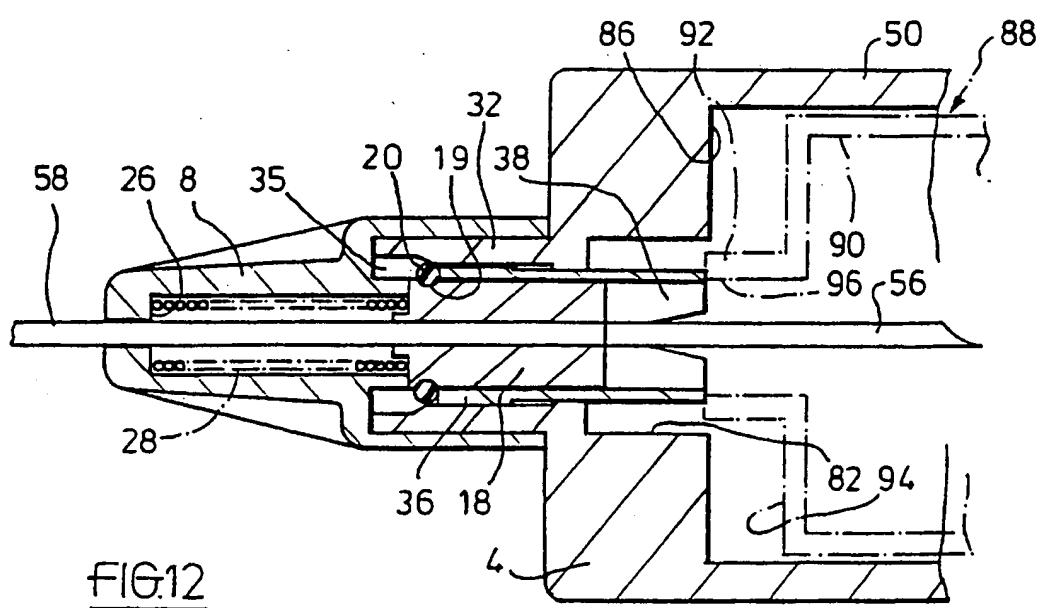
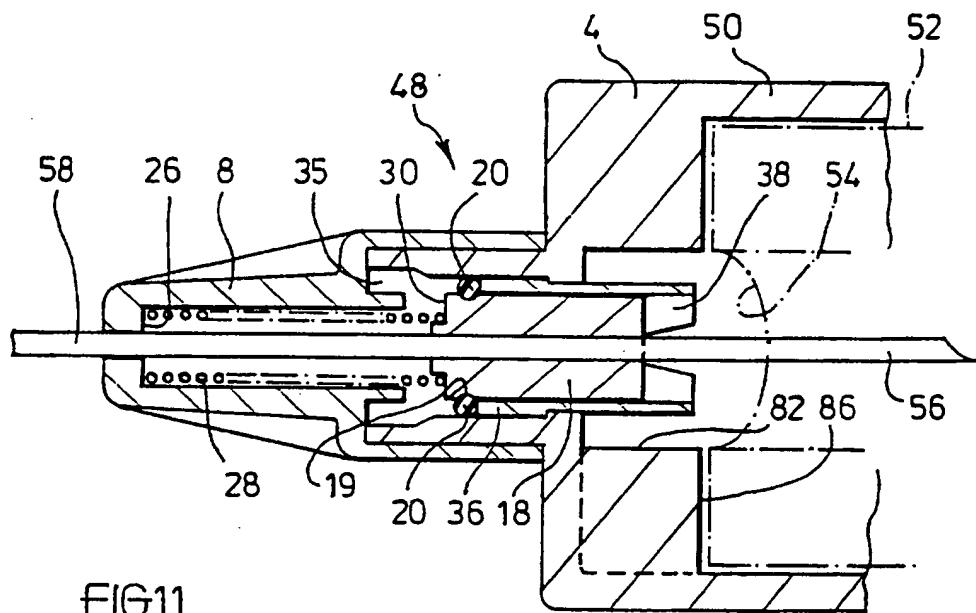


FIG. 10



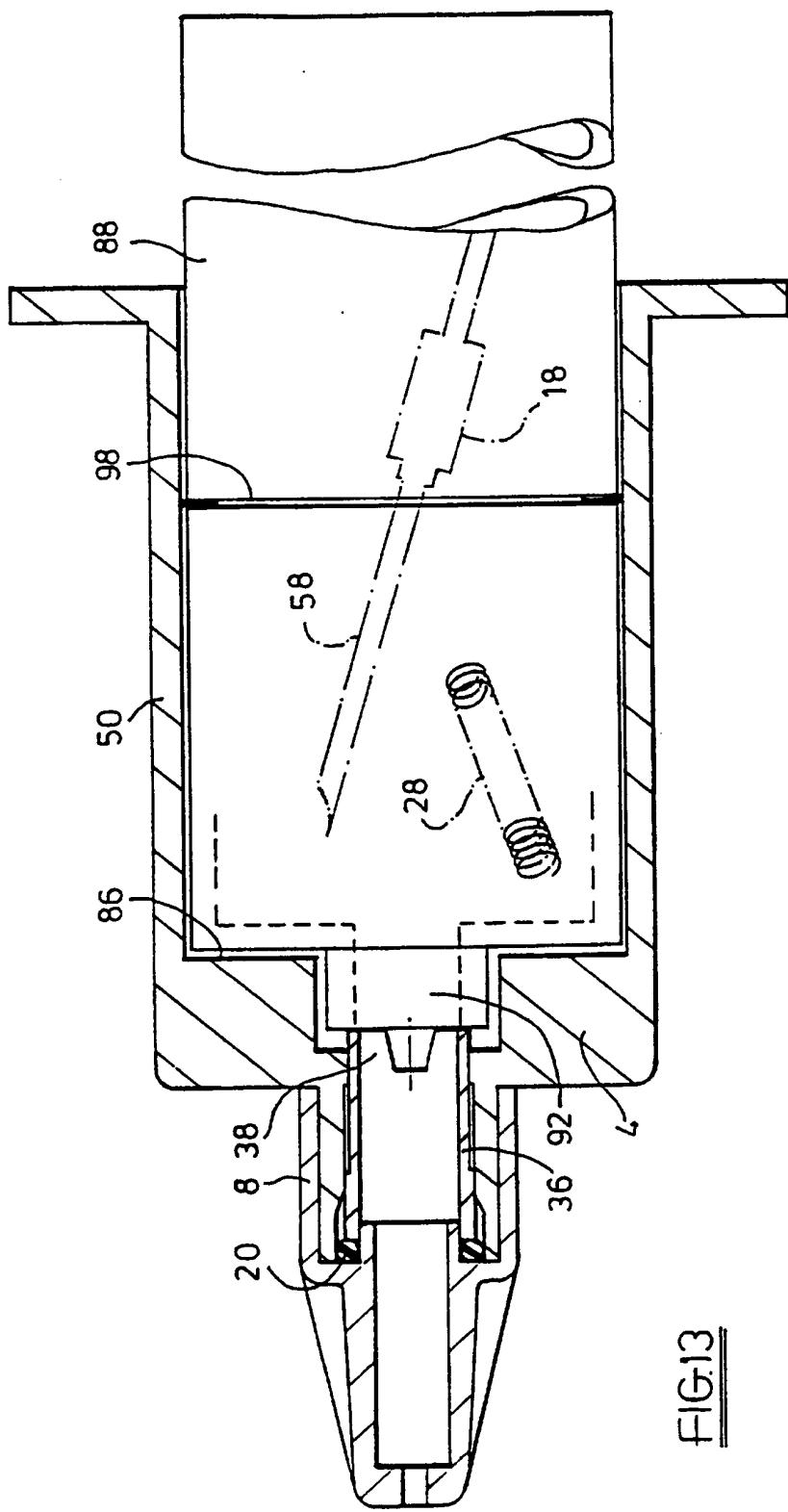


FIG 13

INTERNATIONAL SEARCH REPORT

Inte xnal Application No

PCT/GB 95/01894

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 A61M5/32 A61B5/14 A61M5/19

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	NL,A,8 900 208 (VAN VELZEN ET AL.) 16 August 1990 see page 2, line 1 - line 14 see page 4, line 27 - line 35 see figures 3-6 ---	12
A	US,A,4 966 593 (LENNOX) 30 October 1990 see column 3, line 49 - line 52 see figure 4 ---	1
A	EP,A,0 438 368 (BATLLE) 24 July 1991 see column 3, line 45 - column 4, line 12 see figures 1,2 ---	1
A	US,A,4 973 316 (DYSARZ) 27 November 1990 see column 4, line 55 - column 5, line 11 see figures 2-4 ---	1
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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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2

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INTERNATIONAL SEARCH REPORTInte
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PCT/GB 95/01894**C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 210 160 (IMMUNO AKTIENGESELLSCHAFT FÜR CHEMISCH-MEDIZINISCHE PRODUKTE) 28 January 1987 see page 4, line 16 - line 22 see figure 2 -----	16

INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/GB 95/01894

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
NL-A-8900208	16-08-90	NONE			
US-A-4966593	30-10-90	NONE			
EP-A-438368	24-07-91	AU-B- CA-A- DE-D- DE-T- WO-A-	4959690 2034303 69101112 69101112 9007948	13-08-90 19-07-91 17-03-94 11-05-94 26-07-90	
US-A-4973316	27-11-90	US-A-	4978343 5045081 5125414 5129884	18-12-90 03-09-91 30-06-92 14-07-92	
EP-A-210160	28-01-87	AT-A- CA-A- JP-A- US-A-	382783 1249194 61293443 4735616	10-04-87 24-01-89 24-12-86 05-04-88	

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